K991012

510(k) SUMMARY

as required per 807.92(c)

2. Submitters Name, Address:

Siemens Medical Systems, Inc.
Electromedical Systems Group, PCS
Danvers, MA 01923
Tel: (978) 907-7500
Fax: (978) 750-6879
Official Correspondent: David Simard, Director
Quality Assurance & Regulatory Affairs
Contact person for this submission: Penelope H. Greco
Date submission was prepared: March 19, 1999

3. Trade Name, Common Name and Classification Name:

A. Trade Name:

Siemens INFINITY EEG Pod

B. Common Name, Classification Name, Class and Regulation Number:

Common Name	Classification Number	Class	Regulation Number
Electroencephalograph	84GWQ	II	882.1400
Analyzer, Spectrum, Electroencephalogram Signal	84GWS	I	882.1420

2. Predicate Device Identification:

Aspect Medical Systems, Inc.
Model A-1000 EEG Monitor
510(k) K963644

3. Device Description:

The INFINITY EEG pod is an addition to Siemens SC9000/SC8000/SC7000/SC9000XL INFINITY patient monitoring series. When connected to an INFINITY EEG pod, an INFINITY Modular Bedside Monitor is capable of measuring up to four channels of EEG waveforms. Each waveform has its own parameter box, and each parameter box displays up to three parameters that can be trended, printed, and displayed on a central station.

4. Intended Use:

To monitor the state of the brain by data acquisition of EEG signals.

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Electromedical Systems Group, PCS
16 Electronics Avenue
Danvers, MA 01923
USA
Tel: (978) 907-7500
Fax: (978) 750-6879
Telex: 511958 (Siemensm SD)

5. Table of Device Similarities and differences to predicate device

	Substantial Equivalent Device	Applicant	Explanation of Differences
Manufacturer	Aspect Medical Systems, Inc. A-1000 EEG Monitor and A-1050 EEG Monitor	Siemens Medical Systems Infinity EEG Pod	
510(k) Number	K963644	To be assigned	
Intended Use	To monitor the state of the brain by data acquisition of EEG signals	Same	
Intended Population	All patient populations	Same	
Intended Environment	The intensive care unit, operating room and clinical research	An environment where patient care is provided by Healthcare Professionals	
Computed Parameters	Total Power	Same	
	Delta, Theta, Alpha, Beta Power	Same	
	Spectral Edge Frequency	Same	
	Median Frequency	Same	
	Burst Suppression ratio	Same	
	Power of user defined Band 1	No	Parameter not supported
	Power of user defined Band 2	No	
	Asymmetry	No	
	Bispectral Index	No	
	EMG Power Band 1	No	
	EMG Power Band 2	No	

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6. Assessment of non-clinical performance data for equivalence: Exhibit U

7. Assessment of clinical performance data for equivalence: Exhibit V

8. Biocompatability:
Not applicable

9. Sterilization:
Not applicable

10. Standards and Guidances: FDA Electroencephalograph Devices Guidance for 510(k) Content, Draft Document Version 1.0, November 3, 1997

IEC 601-2-26: 1994, Medical Electrical Equipment: Part 2: Particular Requirements for the Safety of Electroencephalographs

COMPANY CONFIDENTIAL

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 24 1999

Ms. Penelope H. Greco
Regulatory Submissions Manager
Siemens Medical Systems, Inc.
16 Electronics Avenue
Danvers, Massachusetts 01923

Re: K991012
Trade Name: Siemens INFINITY EEG Pod
Regulatory Class: II
Product Code: GWQ and GWS
Dated: March 19, 1999
Received: March 26, 1999

Dear Ms. Greco:

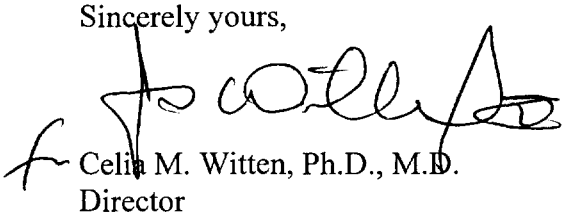
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,



Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K991012

Device Name: **Siemens INFINITY EEG Pod**

Indications for Use:

Siemens INFINITY EEG Pod is indicated for use in the adult, pediatric and neonatal populations, in an environment where patient care is provided by healthcare professionals, i.e. Physicians, Nurses, Technicians, when the professional determines that the device is required to monitor the state of the brain by data acquisition of EEG signals.

MRI Compatibility Statement:
The Siemens INFINITY EEG Pod is not intended for use in a MRI magnetic field.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K991012